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**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE**

LIFESCAN, INC. and  
LIFESCAN SCOTLAND, LTD.,  
Plaintiffs,

v.

SHASTA TECHNOLOGIES, LLC, DECISION  
DIAGNOSTICS CORP., PHARMATECH  
SOLUTIONS, INC., and CONDUCTIVE  
TECHNOLOGIES, INC.,  
Defendants.

Case No. CV11-04494-EJD (PSG)

**LIFESCAN'S OPENING CLAIM  
CONSTRUCTION BRIEF**

Date: April 16, 2013  
Time: 2:00 p.m.  
Place: 5th Floor, Courtroom 4  
Judge: Hon. Edward J. Davila

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1           Plaintiffs LifeScan, Inc. and LifeScan Scotland, Ltd. (collectively "LifeScan") submit  
2 this opening brief on the construction of terms in LifeScan's U.S. Patent Nos. 7,250,105 (the "'105  
3 patent"), 5,708,247 (the "'247 patent"), and 6,241,862 (the "'862 patent"). Copies of these patents  
4 are attached as exhibits to the First Amended Complaint (D.E. 170).<sup>1</sup> Relevant portions of the  
5 patents' prosecution histories are attached to the accompanying Declaration of Sean Marshall.

## 6           **I. INTRODUCTION**

7           This patent infringement case involves disposable test strips that are used by persons  
8 with diabetes to monitor their blood glucose levels. This monitoring assists in detecting  
9 hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose), which can lead to life-  
10 threatening complications if left untreated. Blood glucose testing typically is done by the individual,  
11 at home, several times each day. It is one of the most important things that diabetics can do to  
12 ensure their health and to prevent long-term complications.

13           LifeScan is the leader in the worldwide market for glucose monitoring systems.  
14 LifeScan distributes OneTouch® Ultra® glucose monitoring systems. To use the OneTouch system,  
15 a user places a disposable test strip in the OneTouch meter, uses a lancet to draw a small drop of  
16 blood and places that drop on the test strip. The meter determines the blood glucose level in the  
17 blood sample by measuring the flow of electrical current. Using the OneTouch system, the person  
18 may determine if his or her blood glucose level is within a satisfactory range or if some treatment is  
19 required to increase or decrease the blood glucose level.

20           Defendants make, sell and offer to sell a glucose test strip called the GenStrip for use  
21 with LifeScan's OneTouch Ultra meters as a substitute for LifeScan's OneTouch Ultra test strips.  
22 LifeScan asserts that Defendants infringe claims of the '247 and '862 patents by making and selling  
23 the GenStrip and offering it for sale, and that they are inducing and contributing to the infringement  
24 of the '105 patent.

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26  
27 <sup>1</sup> The '247 patent is Exhibit A to the first Amended Complaint; the '862 patent is Exhibit B and the  
28 '105 patent is Exhibit C.

## II. THE PATENTS AT ISSUE

The '105, '247 and '862 patents disclose and claim features and methods directed at enhancing the accuracy and reliability of glucose measurements using disposable test strips.

### A. The '105 Patent

In the February 21, 2013 hearing on LifeScan's motion for a preliminary injunction, Defendants vacillated between denying and admitting that the GenStrip copies the claimed test strip design of the '105 patent.

The '105 patent is entitled "Measurement of Substances in Liquids." The '105 patent relates to a method to improve the reliability and accuracy of glucose measurements. Prior art measuring glucose measuring devices operated under the general principle that an electric current that is proportional to the concentration of glucose in the test sample is measured between a working and reference sensor part. Col. 1:25-37. However, if the working sensor is not fully covered by blood, the device may yield inaccurate results. Col. 1:39-41. Earlier methods of dealing with this problem did not ensure that the sensors were completely covered by the blood sample, resulting in variable and inaccurate results. Col. 1:41-54.

The '105 patent addresses these problems through an innovative test strip design. The test strip has two working sensors that each generates electrical charge carriers proportional to the amount of glucose in the blood. Col. 2:64-67. One sensor is downstream of the other with respect to blood flow. This allows the current measured at each sensor in response to the application of blood to be compared. Col. 2:10-27.

If the currents measured at each sensor are within a pre-determined range of each other, the sensors are operating properly and both sensors are covered by blood to the same degree. Col. 2:28-39. Because blood flow is restricted so that it must entirely cover the first sensor before covering the second sensor, this ensures that each electrode has been covered completely. Col. 3:43-55. If the difference between the current measured at each sensor is greater than the pre-determined range, the test results will be unreliable (*e.g.*, because of insufficient blood, user error, manufacturing

1 defect, or some other error) and the test done with that strip should be discarded. Col. 2:28-39. Test  
2 strips using the design depicted in the '105 patent thus are self-testing for reliability. Col. 3:3-6.

3 **B. The '247 Patent**

4 The '247 patent is entitled "Disposable Glucose Test Strips, and Methods and  
5 Compositions for Making Same." It is directed towards "an improved disposable glucose test strip  
6 for use in a test meter of the type which receives a disposable test strip and a sample of blood from a  
7 patient and performs an electrochemical analysis of the amount of glucose in the sample." Col.  
8 2:39-44.

9 In general, glucose test strips are made by applying various layers to a substrate,  
10 including what is known as a "working electrode." Col. 1:25-28. In the case of disposable glucose  
11 test strips, this is done by screen printing. Col. 1:42-45. One problem with screen printed glucose  
12 strips in the prior art was that the layers were prone to break when brought into contact with blood  
13 samples. Col. 1:47-50. This resulted in two problems. First, as the components of the electrode ink  
14 were released into solution, they would no longer contribute to the measurements, diminishing the  
15 response to the sample. Col. 1:51-56. Second, the breakup meant that the effective electrode area  
16 would diminish over time. Col. 1:56-58. These two effects could result in current transients that  
17 decrease rapidly over the period of the measurement. Col. 1:59-61. In addition, these effects could  
18 result in a high sensitivity to oxygen, which will compete with the mediator for the enzyme. Col.  
19 1:61-63. This can result in erroneous readings or rejected strips. Col. 1:63-2:2. Another problem  
20 associated with prior art test strips related to the measurement of the glucose. Prior art electrodes  
21 were kinetically controlled and highly dependent on the temperature, resulting in substantial  
22 variations in the measurement of glucose in the sample. Col. 2:3-15.

23 The '247 patent addresses these problems. The working electrode is coated with a  
24 layer that includes not only an enzyme, a conductor, and a mediator, but also a filler with  
25 hydrophobic and hydrophobic surface regions that forms a two-dimensional network. Col. 2:50-60.  
26 This structure has several advantages. For example, the test strip will be dependent on the rate of  
27  
28



1 glucose diffusion and not the rate at which the enzyme can oxidize glucose. Col. 2:62-66. As a  
2 result, the test strip will be relatively insensitive to differences in temperature over relevant  
3 temperature ranges. *Id.* Further, the network is effective to exclude oxygen-carrying red blood cells,  
4 which can interfere with glucose measurements. Col. 2:66-3:3.

5 **C. The '862 Patent**

6 The '862 patent is entitled "Disposable Glucose Test Strips with Integrated  
7 Reagent/Blood Separation Layer." Like the '247 patent, the '862 patent is directed towards "an  
8 improved disposable glucose test strip for use in a test meter of the type which receives a disposable  
9 test strip and a sample of blood from a patient and performs an electrochemical analysis of the  
10 amount of glucose in the sample." Col. 2:58-62. It is a continuation-in-part of the application that  
11 led to the '247 patent.

12 The '862 patent describes improvements in test strip technology, in particular with  
13 regard to preventing red blood cells from contacting the conductive electrode elements. Prior art test  
14 strips often yielded readings that were higher than the true blood glucose level when high hematocrit  
15 levels were present, and conversely yielded readings that were lower than the true value when low  
16 hematocrit levels were present. Col. 2:23-33. Although there were some prior art solutions to this  
17 problem, they generally necessitated higher manufacturing costs, because of the addition of a  
18 manufacturing step involving a separately deposited membrane layer over the reagent-containing  
19 layer, and they often degraded performance in other areas, such as precision. Col. 2:33-42.

20 Rather than having separate barrier and reagent containing layers, the '862 patent  
21 describes, an "integrated reagent/blood separation layer [that] comprises reagents for the  
22 electrochemical detection of the analyte dispersed in a non-conductive matrix effective to exclude  
23 blood cells from the surface" of the conductive surfaces of the electrode. Col. 3:8-13. In the  
24 integrated layer, "reactants such as enzyme, mediator, and glucose move freely ... but interfering  
25 species such as red blood cells containing oxygenated hemoglobin are excluded." Col. 7:6-9.

### III. THE LAW ON CLAIM CONSTRUCTION

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). Claim construction is a question of law for the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-90 (1996).

The *en banc* decision in *Phillips* provides the controlling framework for claim construction. As *Phillips* explains, patent claims are construed in the manner that "'most naturally aligns with the patent's description of the invention.'" 415 F.3d at 1316 (quoting *Renishaw PLC v. Marposs Società per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)). "[T]he focus in claim construction is on 'the meaning of claim terms within the patent,' and not on the abstract meaning of words." *Reflex Packaging Inc. v. Lenovo (United States), Inc.*, No. 5:10-CV-01002-EJD, 2012 U.S. District LEXIS 64594, at \*20 (N.D. Cal. May 8, 2012) (quoting *Phillips*, 415 F.3d at 1321).

In construing claim terms, court should rely mainly on the intrinsic evidence – the claims themselves, the specification and the prosecution history. *Phillips*, 415 F.3d at 1314.

The starting point of claim construction is the words of the claim. Courts generally give terms their "ordinary and customary" meaning," *Epistar Corp. v. U.S. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009), which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313.

A term's usage in the claim may provide insight into its meaning. "The context in which a term is used in the asserted claim can be highly instructive," and "[often] provides a firm basis for construing the term." *Phillips*, 415 F.3d at 1314. Other claims may also provide guidance. *Id.* Courts should avoid a construction that would render other claim language superfluous. *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007). For example, under the doctrine of claim differentiation, a construction that renders a dependent claim superfluous is presumptively incorrect. *SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1361 (Fed. Cir. 2012).

1           The specification is very important. "[C]laims 'must be read in view of the  
2 specification, of which they are a part.'" *Phillips*, 415 F.3d at 1315 (quoting *Markman v. Westview*  
3 *Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*)). "[T]he specification 'is always  
4 highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best  
5 guide to the meaning of a disputed term.'" *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90  
6 F.3d 1576, 1582 (Fed. Cir. 1996)).

7           Although claims must be read in view of the specification, it is a "cardinal sin" to  
8 read limitations from the specification into the claims. *Phillips*, 415 F.3d at 1319-20 (citing *SciMed*  
9 *Life Sys. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001)). A court may  
10 not "confin[e] the claims to those embodiments" found in the patent. *Id.* at 1323. As a general rule,  
11 "it is improper to read limitations from a preferred embodiment described in the specification – even  
12 if it is the only embodiment – into the claims absent a clear indication in the intrinsic record that the  
13 patentee intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898,  
14 913 (Fed. Cir. 2004). "A construction that imposes limitations not found in the claims is erroneous  
15 unless it is supported by an unambiguous restriction elsewhere in the intrinsic record." *Reflex*  
16 *Packaging*, 2012 U.S. Dist. LEXIS 64594, at \*4.

17           In addition, courts may consider the prosecution history, which is the record of  
18 proceedings before the PTO. *Vitronics*, 90 F.3d at 1582. The prosecution history may "provide[ ]  
19 evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317.

20           Evidence beyond the patent and its prosecution history, such as dictionary definitions,  
21 technical treatises or expert testimony, is referred to as extrinsic evidence. By its very nature,  
22 extrinsic evidence provides less insight into what terms mean in the context of the patent. *Phillips*,  
23 415 F.3d at 1317-18. Dictionaries and technical treatises are useful "so long as the dictionary  
24 definition does not contradict any definition found in or ascertained by a reading of the patent  
25 documents." *Id.* at 1322-23 (quoting *Vitronics*, 90 F.3d at 1584 n.6).

Expert testimony is suspect. "[O]pinion testimony on claim construction should be treated with the utmost caution ...." *Vitronics*, 90 F.3d at 1585. Expert testimony on the meaning of a claim term "is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Phillips*, 415 F.3d at 1318. As a result, expert testimony "may only be relied upon if the patent documents, taken as a whole, are insufficient to enable the court to construe disputed claim terms. Such instances will rarely, if ever, occur." *Vitronics*, 90 F.3d at 1585. When the meaning of a term is clear from the intrinsic evidence, "expert testimony regarding the meaning of a claim is entitled to no weight." *Id.* at 1584. "[A] court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'" *Phillips*, 415 F.3d at 1318 (citation omitted); *see also Vitronics*, 90 F.3d at 1583 (warning that the extrinsic evidence cannot be used undermine the public's right to rely on the written record of the patent, *i.e.*, the claims, specification, and prosecution history, to understand the scope of the claimed invention).

While a validity analysis is not a regular component of claim construction, where claim language is ambiguous, that ambiguity generally should be resolved in a manner that would preserve the patent's validity. *See Phillips*, 415 F.3d at 1327. "[C]laims are generally construed so as to sustain their validity, if possible." *Becton, Dickinson & Co. v. Tyco Healthcare Corp.*, 616 F.3d 1249, 1255 (Fed. Cir. 2010) (citation omitted).

#### **IV. THE DISPUTED CLAIM CONSTRUCTION ISSUES**

The constructions LifeScan proposes are consistent with the intrinsic evidence. In contrast, Defendants' constructions violate basic canons of claim construction. Defendants try to read features of a preferred embodiment into broad claim language, which is a "cardinal sin" of claim construction. *Phillips*, 415 F. 3d at 1319-20.

The disputed claim construction issues are discussed below.

**A. Claim Construction for the '105 Patent**

**1. "proportion" and "proportional"**

Claim term	Plaintiffs' construction	Defendants' construction
proportion and proportional	correlated or correlated to	in a fixed ratio

The '105 patent presents only one disputed claim construction issue – the meaning of "proportion" and "proportional" in claims 1 and 3 of the '105 patent. The claims use those terms to describe a relationship that was known in the prior art between: (1) "the concentration of [a] substance [*e.g.*, glucose] in the sample liquid" and the number of "charge carriers generated at [a] working sensor," col. 6:55-61, 8:11-12, and (2) "the concentration of said substance [glucose] in the sample liquid" and the "current measured at each working sensor part," col. 7:13-15. In the context of the claims, "proportion" and "proportional" mean that the number of charge carriers generated is *correlated* to the concentration of the substance being measured in the sample, *i.e.*, that the electric current at each working sensor part is *correlated* to the concentration of the substance being measured in the sample. *See* Marshall Decl., Ex. A (American Heritage Dictionary of the English Language Fourth Edition) at 1406 (defining "proportion" to mean "a relationship between quantities such that if one varies then another varies in a manner dependent on the first" and "proportional" to mean "Forming a relationship with other parts or quantities; being in proportion.").

As the '105 specification makes clear, the patent uses the terms "proportion" and "proportional" to describe a feature of existing glucose measuring systems that was known in the art. The first column of the specification provides background information on the state of the art in the field of glucose measurement (at col. 1:9-54). It states that "known glucose measuring devices now favour an electrochemical measurement." Col. 1:25-27. In these known systems, "[t]he general principle is that an electric current is measured between two sensor parts called the working sensor and reference sensor respectively." Col. 1:27-29. The specification further explains (col. 1:29-33):

The working sensor part comprises a layer of enzyme reagent, the current being generated by the transfer of electrons from the enzyme

substrate, via the enzyme and an electron mediator compound to the surface of a conductive electrode.

The specification then explains (col. 1:33-38):

***The current generated is proportional to*** both the area of the sensor part and also ***the concentration of glucose in the test sample***. Since the area of the working sensor part is supposedly known, ***the electric current should be proportional to the glucose concentration***. (Emphasis added).

The specification then discusses prior art patents disclosing "[k]nown glucose measuring devices ...." Col. 1:25-27. One of those patents is U.S. Patent No. 5,582,697 to Ikeda. Ikeda '697 is referenced in the '105 specification at col. 1:41-44 and cited in the prosecution history. It is part of the intrinsic record. *See Powell v. The Home Depot, Inc.*, 663 F.3d 1221, 1231 (Fed. Cir. 2011) ("prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence."). The Ikeda '697 patent uses the term "proportional" in the same way as the '105 patent when it states that "***[t]he obtained current value is in proportion to the concentration of the substrate in the sample liquid***." Marshall Decl., Ex. B (Ikeda '697) at col. 8:9-19 (emphasis added). U.S. Pat. No. 5,650,062 (Ikeda), which also is part of the intrinsic record, is identical in relevant respects. *Id.*, Ex. C (Ikeda '062) at col. 8:11-13.

Other prior art patents that are part of the intrinsic record use the terms "proportion" and "proportional" the same way.<sup>2</sup> For example:

- U.S. Pat. No. 5,820,551 (Hill) states that "***[t]he current*** flowing [through the electrodes dipped into a glucose-containing solution] ***is proportional to the glucose concentration***." Marshall Decl., Ex. D at col. 8:56-57 (emphasis added).
- U.S. Pat. No. 6,004,441 (Fujiwara) states that "***[e]lectric current flows in proportion to the density of glucose***." *Id.*, Ex. E at col. 1:33-34 and col. 3:31-32 (emphasis added).

These prior art patents are part of the intrinsic record. *See* Marshall Decl., Ex. F at LSS00282964; *see also Powell*, 663 F.3d at 1231. They use the terms "proportion" and "proportional" in the same

<sup>2</sup> *See Arcelor Mittal France v. AK Steel Co.*, 700 F.3d 1314, 1321 (Fed. Cir. 2012) ("Prior art can help to demonstrate how disputed term is used by those skilled in the art.").

1 sense as the '105 patent, as meaning "correlated," in referring to the correlation between the  
2 concentration of glucose in the liquid sample and the current generated.

3 Defendants advocate a different construction of "proportion" and "proportional," as  
4 meaning "in a fixed ratio." That construction is at odds with the usage of these terms in the patent  
5 and in the prior art. Under Defendants' definition, the claim would require that glucose  
6 concentration be calculated from the measured current by multiplying a simple constant, *e.g.*,  
7 glucose equals three times or five times the measured current. Defendants' construction finds  
8 support in the realm of theoretical mathematics, but it has no relation to how persons of skill in the  
9 art of disposable glucose test strips used the terms "proportion" and "proportional."

10 In fact, in order for Defendants' construction to be correct, then the usage of  
11 "proportion(al)" in the patent and in the prior art would have to be wrong. Defendants admit this.  
12 They argue that when "proportional" is given their claim construction, then "[t]he science set forth in  
13 the claims of the '105 Patent is simply incorrect," D.E. 203 at 33, because "no known device/method  
14 can 'measure an electric current ... proportional to the concentration of said substance' ...." *Id.*,  
15 quoting D.E. 206 (Wang Decl.), ¶¶ 27-28. Under their construction, the patent would not cover the  
16 preferred embodiment or any other operable embodiment. Such a construction "'is rarely, if ever  
17 correct ....'" *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1290 (Fed. Cir.  
18 2010) (quoting *Vitronics*, 90 F.3d at 1583-84). Moreover, if Defendants' construction is correct, then  
19 prior art patents that use the term "proportion(al)" the same way would also be wrong.<sup>3</sup>

20 Clearly, *something* is very wrong when one applies Defendants' construction. Either:  
21 (1) Defendants' construction is correct, in which case "the science set forth in the claims of the '105  
22 Patent," and the usage of "proportion" and "proportional" in the patent and the prior art "is wrong,"  
23

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24  
25 <sup>3</sup> In their opposition to LifeScan's preliminary injunction motion, Defendants asserted that the  
26 device disclosed in the prior art Winarta '229 patent "***necessarily*** 'measure[s] electric current ...  
27 ***proportional*** to the concentration' of glucose," subject, of course, to their inconsistent argument that  
28 such a scientific relationship "is simply incorrect." D.E. 203 at 23 (emphasis added).



1 D.E. 203 at 33; or (2) the patent and the prior art are consistent with the usage of these terms by  
 2 persons skilled in the art and Defendants' claim construction is wrong.<sup>4</sup>

3 Defendants' Instructions for Use (IFU) for the GenStrip help provide the answer.<sup>5</sup> If  
 4 Defendants' claim construction were correct, then the GenStrip – like every "known device/method"  
 5 – could not "measure an electric current ... proportional to the concentration of said substance." D.E.  
 6 203 at 33. But the IFU that Defendants place in every GenStrip package, with the FDA's clearance,  
 7 echo the claim language of the '105 patent by stating that the GenStrip uses the same "principal  
 8 [sic]" as the disputed claim limitation: "Glucose in blood combines with an enzyme in the  
 9 [GenStrip]. ***This produces an electric current in the Meter in proportion to the glucose level.***"  
 10 D.E. 215-1 (Meyerhoff Supp. Decl.), Ex. 2 at PHARM0005237 (emphasis added). Having admitted  
 11 to the FDA and to the public that the GenStrip "produces an electric current ... ***in proportion*** to the  
 12 glucose level," *id.*, Defendants cannot argue now that this is impossible under the correct  
 13 understanding of "proportion." Presumably, the FDA was right on the science and in its usage of "in  
 14 proportion." What is wrong is Defendants' claim construction.

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16  
 17 <sup>4</sup> The technical literature includes many similar examples. *See, e.g.*, D.E. 215-1 [Meyerhoff Decl.],  
 18 at ¶¶ 146-59 and Ex. 28, Meric, B. et al., *Performance of Precision G Blood Glucose Analyzer With*  
 19 *a New Test Strip G2b on Neonatal Samples*, 48 CLINICAL CHEM. 179-80, Jan. 2002, Vol 48 No. 1  
 20 ("***The electrical current***, detected by the electrodes on the test strip, ***is proportional to the***  
 21 ***concentration of glucose in the specimen.***") (emphasis added); Ex. 29, Johnston, J. et al., *What*  
 22 *should we measure in the diabetic patient and how does this respond to therapy?*, 54:1 BR J CLIN  
 23 PHARMACOL. 54(1):81-86, 2002 July ("***The current produced was proportional to the glucose***  
 24 ***concentration.***") (emphasis added); Ex. 30, Feldman, B. (Abbott Diabetes Care), *Electrochemical*  
 25 *Blood Glucose Test Strips For People With Diabetes*, ELECTROCHEMISTRY ENCYCLOPEDIA, October  
 26 2009, available at <http://electrochem.cwru.edu/encycl/art-g01-glucose.htm> ("The electrochemical  
 27 blood glucose test strip . . . then produces, in conjunction with a test meter, ***an electrical current***  
 28 which is ***proportional to the blood glucose concentration.***") (emphasis added).

24 <sup>5</sup> It is appropriate to consider the accused product in connection with claim construction. *Jang v.*  
 25 *Boston Scientific Corp.*, 532 F.3d 1330, 1337 (Fed. Cir. 2008) ("We have previously emphasized the  
 26 importance of the context provided by an analysis of the accused device when ruling on claim  
 27 construction ...."); *Lava Trading, Inc. v. Sonic Trading Mgt., LLC*, 445 F.3d 1348, 1350 (Fed. Cir.  
 28 2006) ("Without knowledge of the accused products, this court ... lacks a proper context for an  
 accurate claim construction.").



Defendants' construction is at odds with how persons of skill in this art use the terms "proportion" and "proportional," in the '105 specification and in prior art patents that are part of the intrinsic record. A construction – like Defendants' construction – that treats the patent and the prior art as nonsensical cannot be correct. *AIA Eng'g Ltd. V. Magotteaux Int'l S/A*, 657 F.3d 1264, 1276 (Fed. Cir. 2011) ("We strive, where possible, to avoid nonsensical results in construing claim language."); *Becton Dickinson*, 616 F.3d at 1255 ("A claim construction that renders asserted claims facially nonsensical 'cannot be correct. '" (citation omitted).

As LifeScan's expert Dr. Meyerhoff has explained, Defendants' construction is "preposterous." D.E. 215-1, ¶ 152. In the real world, glucose measurements do not exist "in a fixed ratio" of concentration to current, as required by Defendants' construction. In the real world of electrochemical measurements, adjustments are needed to account for environmental factors and background noise.<sup>6</sup> A correct construction must take into account these real world facts, and actual usage by persons of skill in the art. *See K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1365 (Fed. Cir. 1999) ("claim construction is firmly anchored in reality by the understanding of those of ordinary skill in the art"). LifeScan's construction is consistent with real world usage of proportion(al) by persons of skill in the art. Defendants' construction is at odds with that usage. Defendants' expert Dr. Wang concedes that it makes sense to refer to the "measured current [as] be[ing] correlated to the glucose construction." D.E. 206, ¶ 26 (underlining in original). That is LifeScan's construction.

## **B. Claim Construction for the '247 Patent**

### **1. "a filler having both hydrophobic and hydrophilic surface regions"**

Claim term	Plaintiffs' construction	Defendants' construction
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<sup>6</sup> See D.E. 215-1 (Meyerhoff Supp. Decl.), ¶ 148 ("[O]ne of skill in the art would understand that the current measurement would need to be corrected in order for glucose concentration to be accurately calculated from the measured current. Background current from the sample as well as environmental conditions such as temperatures will almost always have an effect [on] test results. One of skill in the art would understand that these factors need to be corrected for in order to calculate a glucose concentration from the measured current.").

a filler having both hydrophobic and hydrophilic surface regions	ordinary meaning <i>or</i> additive having some surface regions that lack an affinity for water and some surface regions that have an affinity for water	silica broken down to expose hydrophilic inner portions so that the actual particles have separate regions that attract and repel water.
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Claims 1 and 24 of the '247 patent include the phrase "a filler having both hydrophobic and hydrophilic surface regions." This phrase does not require construction, except to the extent it may assist the jury to have definitions of "hydrophobic" and "hydrophilic."

"Hydrophobic" means lacking an affinity for water or repels water and "hydrophilic" means having an affinity for water or attracts water. *See* Marshall Decl., Ex. G, Webster's New Collegiate Dictionary (1981) at 556 (defining "hydrophilic" as "of, relating to, or having a strong affinity for water" and "hydrophobic" as "lacking affinity for water"); *id.*, Ex. H, McGraw-Hill Dictionary of Scientific and Technical Terms, (1994) at 971 (defining "hydrophilic" as "having an affinity for, attracting, adsorbing or absorbing water" and hydrophobic as "lacking an affinity for, repelling, or failing to adsorb or absorb water").

The parties' main disagreement on this phrase involves the meaning of "filler." That term has an ordinary and accustomed meaning, as meaning an additive. *See* Marshall Decl., Ex. G, Webster's New Collegiate Dictionary (1981) at 425 (defining "filler" as "*a substance added to a product* (as to increase bulk, weight, viscosity, opacity, or strength).") (emphasis added); *id.*, Ex. H, McGraw-Hill Dictionary of Scientific and Technical Terms, (1994) at 753 (defining "filler" as "*an inert material added to paper, resin, bituminous material, and other substances to modify their properties and improve quality.*") (emphasis added). Nothing in the patent or the prosecution history supports a different meaning.

Instead of accepting the ordinary meaning of "filler," Defendants construe that general term to require a specific material, *i.e.*, silica. That is not a proper claim construction. Silica is a material used in the preferred embodiment – not the meaning of the broad term "filler." *See* '247 patent at col. 2:61-62 ("*[p]referred fillers are non-conductive silica fillers.*"); col. 4:10-12 ("*A preferred filler for use in the coating 17 is silica.*") (all emphasis added). Defendants commit the

1 "cardinal sin" of claim construction by treating this feature of the preferred embodiment as a  
2 definition of "filler." *Philips*, 415 F.3d at 1319-20. Their construction "improper[ly] ... read[s]  
3 limitations from a preferred embodiment described in the specification ... into the claims absent a  
4 clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel-*  
5 *Flarsheim*, 358 F.3d at 913. "A construction that imposes limitations not found in the claims is  
6 erroneous unless it is supported by an unambiguous restriction elsewhere in the intrinsic record."  
7 *Reflex Packaging*, 2012 U.S. Dist. LEXIS 64594, at \*4.

8           The prosecution history confirms that the term "filler" is not limited to silica. During  
9 prosecution, the examiner initially rejected certain claims because "the only example that is  
10 disclosed is silica." Marshall Decl., Ex. I at LSS00001948. In response, the applicant explained that  
11 "[other] examples are not required for enablement." *Id.*, Ex. J at LSS00001958. The examiner then  
12 withdrew the rejection. The "statement of reasons for allowance" states that "[t]he prior art of record  
13 fails to teach the key to the applicants instant invention which is the inclusion of a filler having  
14 hydrophobic and hydrophilic surface regions." *Id.*, Ex. K at LSS00001967. The examiner did not  
15 require the addition of silica as a limitation of the claims.

16           The doctrine of claim differentiation provides further support for LifeScan's  
17 construction. "'Claim differentiation' refers to the presumption that an independent claim should not  
18 be construed as requiring a limitation added by a dependent claim." *Curtiss-Wright Flow Control*  
19 *Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006). This doctrine is applicable here because  
20 claim 3 of the '247 patent recites "[t]he test strip of claim 2, wherein the filler is silica," and claim 26  
21 similarly recites "the method of claim 25, wherein the filler is silica." Under Defendants'  
22 construction, the filler of claims 2 and 25 would be defined as silica, making claims 3 and 26  
23 completely superfluous. Such a construction is presumptively incorrect. *See Wenger Mfg., Inc. v.*  
24 *Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001) ("Claim differentiation ... is clearly  
25 applicable when there is a dispute over whether a limitation found in a dependent claim should be  
26 read into an independent claim, and that limitation is the only meaningful difference between the two  
27

claims."); *Phillips*, 415 F.3d at 1315; *SanDisk*, 695 F.3d at 1361. The presumption of claim differentiation is "especially strong" here because the feature Defendants are trying to "read into" the general term "filler," *i.e.*, silica, is "the only meaningful difference" between claims 2 and 3 and "the only meaningful difference" between claims 25 and 26. *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

## 2. "network"

Claim term	Plaintiffs' construction	Defendants' construction
Network	ordinary meaning <i>or</i> structure that provides a barrier to the passage of red blood cells	a structure, barrier, or net arrangement of fibrous strands or chains that create a honeycomb shape to catch red blood cells

Claims 1 and 24 of the '247 also recite a "network." This term does not have any special meaning in the '247 patent, and does not require construction. As explained in the patent, the network provides a barrier to the passage of red blood cells. Col. 2:66-3:3; 4:41-44. Thus, if the Court deems it necessary to provide a construction for "network," it should be construed as a structure that provides a barrier to the passage of red blood cells.

Here, as elsewhere, Defendants violate basic axioms of claim construction by improperly reading features of the preferred embodiment into the claims. Defendants propose limiting the term "network" to "a structure, barrier or net arrangement of fibrous stands or chains that create a honeycomb shape to catch red blood cells." Defendants cannot point to any intrinsic evidence, or any dictionary or treatise, that defines a "network" as having these features.

To be sure, the patent explains that "*in Example 1*, ... [there are] layers of two-dimensional networks which take form as a kind of honeycomb." Col. 4:35:39 (emphasis added). But Example 1 is an example only – not a definition of "network." The Federal Circuit "does not import examples from the specification into the claims." *In re Omeprazole Patent Litigation*, 483 F.3d 1364, 1372 (Fed. Cir. 2007); *see also The Medicines Co. v. Dr. Reddy's Laboratories, Ltd.*, No. 11-2456 (PGS), 2013 U.S. Dist. LEXIS 536, at \*24 (D. N.J. Jan. 2, 2013) ("the Federal Circuit has made clear that examples in the specification should not be used to limit claim scope."). There is no

support in the patent or prosecution history for limiting the general term "network" to an "arrangement of fibrous strands or chains that create a honeycomb shape."

Apart from Defendants' effort to read these added limitations into the definition of "network," the parties' constructions are somewhat similar: "structure that provides a barrier to the passage of red blood cells" (in LifeScan's construction) versus "a structure ... that [ ] catch[es] red blood cells" (in Defendants' construction). The patent never mentions "catching" red blood cells. Rather, it describes a structure where "[e]nzyme, mediator and glucose move freely ... but interfering species such as red blood cells ... are excluded." Col. 4:41-44. If the Court construes the term network, LifeScan's construction should be adopted.

### 3. "working coating"

Claim term	Plaintiff's construction	Defendant's construction
working coating	a layer that contains the enzyme and mediator, is permeable to glucose, and provides a barrier to the passage of red blood cells	ordinary meaning <i>or</i> working coating is not a working layer

Claim 1 of the '247 patent recites a "working coating."<sup>7</sup> The specification describes the coating (or layer, which the patent uses interchangeably with coating) as allowing "[e]nzyme, mediator, and glucose [to] move freely ..., but interfering species such as red blood containing oxygenated hemoglobin are excluded." Col. 4:41-44; *see also* col. 5:19-24 (the second (working) layer "isolates the conductive base from contact with oxygen-carrying red blood cells, thus reducing the effects of oxygen."). LifeScan's construction appropriately construes the "working layer" by reference to the work it performs.

Defendants' position is that if this Court construes "working coating," it should be construed as "not a working layer." Such a construction would be incorrect. To be sure, a patentee's use of different terms often "implies that they have different meanings ...." *Baran v. Medical*

<sup>7</sup> As discussed above, LifeScan contends that the term "network" does not require construction. In the event the Court disagrees and adopts either LifeScan's or Defendants' construction of "network," then LifeScan would agree with Defendants that the terms "working coating" and "working layer" do not require construction.

1 *Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010). "[B]ut that implication is overcome  
2 where, as here, the evidence indicates that the patentee used the two terms interchangeably." *Id.*  
3 (citing *Tehrani v. Hamilton Med., Inc.*, 331 F.3d 1355, 1361 (Fed. Cir. 2003)).

4 Here, the '247 patent use the words "coating" and "layer" interchangeably. For  
5 example, the specification uses reference numeral **17** interchangeably to refer to both a working  
6 coating and working layer. *See* col. 3:44-46 ("... the working coating **17** of the electrode assembly  
7 **22** ..."); col. 4:4-5 ("The key to the performance achieved using the present invention is in the nature  
8 of the coating **17**"); col. 5:16-18 ("In th[e] embodiment [shown in Fig. 7], a second working layer **71**  
9 is disposed over the first working layer **17**"); col. 5:31-32 ("A non-conducting formulation for  
10 preparation of working layer **17** was made as follows.").

11 Because the patent uses the words "working coating" and "working layer"  
12 interchangeably, they have the same meaning in the '247 patent. *See Baran*, 616 F.3d at 1316 ("the  
13 terms 'releasably' and 'detachable' have the same meaning in the '798 patent ...."); *Bancorp Serv.,*  
14 *LLC v. Hartford Line Ins. Co.*, 359 F.3d 1367, 1372 (Fed. Cir. 2004) ("the term 'surrender value  
15 protected investment' ... has essentially the same meaning as the term 'stable value protected  
16 invention' ... as used in the '792 patent ...."); *Tate Access Floors v. Maxcess Techs.*, 222 F.3d 958,  
17 968 (Fed. Cir. 2000) ("the terms 'body portion' and 'layer' are used interchangeably in the  
18 specification, and therefore should be construed in the same manner.").

#### 19 4. "working layer"

20 Claim term	Plaintiff's construction	Defendant's construction
21 working layer	22 see the construction of working 23 coating	24 indefinite in violation of 35 U.S.C. § 112 with respect to its use in Claim 2. PROPOSED CONSTRUCTION: ordinary meaning or working layer is not a working coating

26 Claim 2 of the '247 patent is a dependent claim, reciting "[t]he test strip of claim 1,  
27 wherein the working layer is non-conductive." Because the terms "working coating" and "working

layer" are used interchangeably in the '247 patent, they have the same meaning and should be construed accordingly. *See Baran*, 616 F.3d at 1316 (construing "releasably" and "detachable" as "hav[ing] the same meaning"); *Bancorp*, 359 F.3d at 1371 (construing "surrender value protected investment" and "stable value protected invention" as having the same meaning); *Tate Access*, 222 F.3d at 968 (construing the terms "body portion" and "layer" "in the same manner.").

Defendants disagree. Their position is that the term "working layer" in claim 2 is indefinite under 35 U.S.C. § 112(2), and thus invalid, because it does not appear verbatim in independent claim 1, from which claim 2 depends. As a result, Defendants' argue, the term "the working layer" does not have an antecedent basis in claim 1. But the term "working coating" *does* appear in claim 1 and, as discussed above, the '247 patent uses the terms "working layer" and "working coating" interchangeably.

As the Federal Circuit has held, "an antecedent basis can be present by implication," *Energizer Holdings v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370 (Fed. Cir. 2006), and the lack of an explicit antecedent basis does not render a claim indefinite "[w]hen the meaning of the claim would reasonably be understood by persons of ordinary skill when read in light of the specification ...." *Id.* Here, persons of skill in the art would appreciate that the term "working coating" in claim 1 implicitly provides an antecedent basis for the interchangeable term "working layer" in claim 2. There is no indefiniteness problem. *Id.*, 435 F.3d at 1370-71 (reversing a finding of indefiniteness and holding that "'anode gel' is by implication the antecedent basis for 'said zinc anode'"); *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359 (Fed. Cir. 2001).

In asserting indefiniteness, Defendants face a very heavy burden:

[A] claim is not indefinite merely because it poses a difficult issue of claim construction; if the claim is subject to construction, *i.e.*, it is not insolubly ambiguous, it is not invalid for indefiniteness. .... That is, if the meaning of the claim is discernible, "even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).



*Bancorp*, 359 F.3d at 1371. This approach "accord[s] respect to the statutory presumption of validity, ... and ... 'protect[s] the inventive contribution of patentees, even when the drafting of their patents has been less than ideal.'" *Id.* (quoting *Exxon*, 265 F.3d at 1375). Applying this approach, "'close questions of indefiniteness ... [are] resolved in favor of the patentee.'" *Id.* (quoting *Exxon*, 265 F.3d at 1380).

Here, the term "working layer" is "subject to construction, i.e., it is not insolubly ambiguous ...." *Bancorp*, 359 F.3d at 1371. Thus, it is "not invalid for indefiniteness." *Id.*; *see also Bose*, 274 F.3d at 1359. The antecedent basis for "working layer" in claim 2 is the interchangeable term "working coating" in claim 1. Even if there were no explicit antecedent basis for "working layer" in claim 2, the claim still would not be indefinite because "the scope of the claim would be reasonably ascertainable by those skilled in the art." *Bose*, 274 F.3d at 1359. The antecedent basis for "working layer" can be present by implication, *Energizer Holdings*, 435 F.3d at 1370-71, and it is present in the term "working coating."

As a fallback, Defendants argue that if "working layer" is not indefinite, then it should be construed as "not a working coating." That is incorrect. As discussed above, the patent uses the terms "working coating" and "working layer" interchangeably and they should be given the same meaning. *Baran*, 616 F.3d at 1316; *Bancorp*, 359 F.3d at 1371; *Tate Access*, 222 F.3d at 968.

## C. Claim Construction for the '862 Patent

### 1. "integrated reagent/blood separation layer"

Claim term	Plaintiffs' construction	Defendants' construction
integrated reagent/blood separation layer	a single layer that contains reagents, is permeable to the analyte, and provides a barrier to the passage of red blood cells	silica combined with reagents for electrochemical detection of analyte that provides a barrier to the passage of red blood cells

Claims 1 and 22 of the '862 patent recite an "integrated reagent/blood separation layer." This layer is a key improvement over prior art test strips. As described above, the '862 patent states that electrochemical glucose detection is complicated by as a result of interference from



1 red blood cells in the sample. Col. 2:23-26. Prior art methods of preventing red blood cell  
2 interference, while allowing glucose to permeate the layer to reach the electrode for measurement,  
3 involved applying a separately deposited exclusion layer (in addition to a layer that contained the  
4 reagents for electrochemical detection). Col. 2:33-38. The inventors sought to find a way to limit  
5 red blood cell response without this extra manufacturing step. Col. 2:39-42. Thus, the inventors  
6 created an "integrated reagent/blood separation layer" to provide a single layer that both allows for  
7 the electrochemical detection of an analyte and excludes red blood cells, *i.e.*, a single layer that  
8 contains reagents, is permeable to the analyte (glucose), and provides a barrier to the passage of red  
9 blood cells. *See* col. 3:8:13 ("The integrated reagent/blood separation layer comprises reagents for  
10 the electrochemical detection of the analyte dispersed in a non-conductive matrix effective to  
11 exclude blood cells from the surface of the first conductive element while permitting access to the  
12 first conductive element by soluble electroactive species.").

13           These features are specifically recited in claims 1 and 22 ("integrated reagent/blood  
14 separation layer comprising reagents for the electrochemical detection of the analyte dispersed in a  
15 non-conductive matrix effective to exclude blood cells from the surface of the first conductive  
16 element while permitting access to the first conductive element by soluble electroactive species.").

17 LifeScan's construction makes clear that the explicit limitations of the integrated reagent/blood  
18 separation layer are carried out by a single layer, rather than, *e.g.*, a combination of a reagent-  
19 containing layer and a separately applied blood separation layer, as in the prior art. *See* col. 2:33-42.

20           Here, as elsewhere, Defendants commit a "cardinal sin" of claim construction,  
21 *Phillips*, 415 F.3d at 1319-20, by reading a feature of the preferred embodiment – silica – into the  
22 claims. That is improper. *See* pages 7, 14-15, *supra*. When the patentees wanted to make silica a  
23 requirement of a particular claim they did so expressly – *e.g.*, in claims 7, 18, 26 and 30 of the '862  
24 patent – by reciting "silica" as an express claim limitation. They did *not* do so in claims 1 and 22 of  
25 the '862 patent, and it would be improper to read a silica limitation into those claims.

## 2. "matrix"

Claim term	Plaintiffs' construction	Defendants' construction
matrix	Ordinary meaning <i>or</i> substance or structure in which something is contained	A two dimensional network. A network is a structure, barrier, or net arrangement of fibrous strands or chains that create a honeycomb shape to block red blood cells.

Claims 1 and 22 recite the term "matrix." That term has no special meaning in the '862 patent and does not require construction. Alternatively, "matrix" could be construed consistent with its customary and ordinary meaning as meaning a "substance or structure in which something is contained." *See* Marshall Decl., Ex. L at 772 (American Heritage Dictionary (1982) ("matrix... 1. A situation or surrounding substance within which something originates, develops, or is contained."); D.E. 235-1 at 9 ("Material in which something is enclosed or embedded. Merriam Webster Dictionary online.")).

Once again, Defendants commit the error of importing limitations from the specification into the claim and limiting a general claim term to a preferred embodiment. This is improper. *See* page 7, *supra*. Defendants start by defining matrix to mean "a two-dimensional network" and then argue that the definition of "matrix" has all the features that they (improperly) include in their construction of "network." None of this is correct. The patentees' use of the terms "network" and "matrix" creates a presumption that "the use of these different terms in the claims connotes different meanings." *CAE Screenplates v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) (citation omitted). No intrinsic evidence overcomes that implication. Moreover, as discussed above (at pages 16-17), the added limitations that Defendants try to read into the term "network" are not part of the meaning of that term, let alone part of the definition of the different term "matrix."

In addition, Defendants' construction improperly treats other claim language as superfluous. For example, claim 1 recites a test strip comprising "a non-conductive matrix *effective to exclude blood cells ....*" Defendants' construction would improperly render this phrase

superfluous by reading in the function of "block[ing] blood cells." *See Stumbo*, 508 F.3d at 1362 (denouncing claim constructions that render phrases in claims superfluous).

### 3. "effective to exclude blood cells from"

Claim term	Plaintiffs' construction	Defendants' construction
effective to exclude blood cells from	that provides a barrier to the passage of blood cells to	sufficient to render the test strip insensitive to the varying hematocrit of patients

Claims 1 and 22 of the '862 patent include the phrase "effective to exclude blood cells from ...." Consistent with the ordinary meaning and specification of the '862 patent, a layer that is "effective to exclude blood cells" is one that provides a barrier to the passage of blood cells. As the specification states, the "integrated reagent blood/separation layer provides a barrier to the passage of interferents such as cells and macromolecules." Col. 4:39-41.

Defendants again improperly read limitations from the specification into the claims by limiting general claim language to particular features of a preferred embodiment. As described in the specification, features of "[p]referred integrated reagent/blood separate layers ... render[ ] the test strip substantially insensitive to the hematocrit of the patient." Col. 3:24-30 (emphasis added). But this is a feature of a preferred embodiment – not a limitation of claims 1 and 22. There is no basis for reading into the claims the feature of a preferred embodiment relating to hematocrit insensitivity.

### 4. "the first conductive species"

Claim term"	Plaintiffs' construction	Defendants' construction
the first conductive species	the first conductive element	indefinite in violation of 35 U.S.C. § 112

Claim 22 of the '862 patent uses the term "the first conductive species." Persons skilled in the art would readily understand that the "the first conductive species" in claim 22 refers to a "first conductive element," which is recited earlier in the claim.

The prosecution history confirms this. Original claim 1 of the application for the '862 patent used the same language ("the first conductive species") that appears in issued claim 22. Marshall Decl., Ex. M, at LSS00002160. The patent examiner recognized that the word "species" should have been "element." *Id.*, Ex. N at LSS00002190. The applicants amended claim 1 in accordance with the examiner's comment, confirming that "the first conductive element," recited earlier in the claim, provided the antecedent basis for this term. *Id.*, Ex. O at LSS00002205-06. Persons of skill in the art likewise would understand that the phrase "the first conductive element" in claim 22 implicitly provides the antecedent basis for "the first conductive species" recited later in the claim. *Energizer Holdings*, 435 F.3d at 1370-71.

Defendants argue that the claim term is indefinite in violation of 35 U.S.C. § 112, rendering the claim invalid. Once again, Defendants cannot meet the heavy burden for an indefiniteness argument. They cannot show that the term is "insolubly ambiguous," and thus not "subject to construction ...." *Bancorp*, 359 F.3d at 1371. As discussed above, "an antecedent basis can be present by implication," *Energizer Holdings*, 435 F.3d at 1370-71, and lack of an explicit antecedent basis does not present an indefiniteness problem "[w]hen the meaning of the claim would reasonably be understood by persons of ordinary skill when read in light of the specification ...." *Id.* Here, persons of skill in the art would appreciate that the term "first conductive element" in claim 1 implicitly provides an antecedent basis for the term "first conductive species" in claim 2. There is no indefiniteness problem. *Id.*, 435 F.3d at 1370-71. *See* pages 19-20, *supra*.

##### 5. "the reagent layer"

Claim term	Plaintiffs' construction	Defendants' construction
the reagent layer	integrated reagent/blood separation layer	indefinite in violation of 35 U.S.C. § 112

Defendants make similar arguments with respect to "the reagent layer" in claim 23. They assert that "the reagent layer" is indefinite as lacking an antecedent basis because claim 22 (from which claim 23 depends) refers to an "integrated reagent/blood separation layer," rather than a

1 "reagent layer." Persons of skill in the art would readily understand that the reference in claim 23 to  
 2 "the reagent layer" implicitly has its antecedent basis in claim 22's reference to an "integrated  
 3 reagent/blood separation layer." *See Energizer Holdings*, 435 F.3d at 1370-71. The applicants noted  
 4 an inconsistency in language when they amended original claim 22 to change the original term  
 5 "reagent layer" to "integrated reagent/blood separation layer." Marshall Decl., Ex. O, at  
 6 LSS00002205-06. Although they neglected to make the same change to claim 23, *id.*, Ex. M, at  
 7 LSS00002164, it would readily be understood by persons of skill in the art, and is not indefinite.

## 8 **V. CONCLUSION**

9 This Court should adopt LifeScan's proposed constructions.

10 Dated: March 7, 2013

11 /s/ Gregory L. Diskant  
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 15 and LifeScan Scotland, Ltd.